

FORM PTO-1390
(REV. 9-2001)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

01795/HG

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/018238

INTERNATIONAL APPLICATION NO.

PCT/EP00/05341

INTERNATIONAL FILING DATE

JUNE 9, 2000

PRIORITY DATE CLAIMED

JUNE 10, 1999

TITLE OF INVENTION

PERSONAL CARE FORMULATIONS

APPLICANT(S) FOR DO/EO/US Kevan HATCHMAN, Elvin LUKENBACH, Laura MCCULLOCH and
Benjamin WIEGAND

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau). (As WO 00/76460 A2)
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

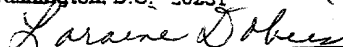
Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☒ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:

- (i) Copy of WO 00/76460 A2
- (ii) PCT/ISA/210 (Search Report)
- (iii) PCT/IB/304 (Priority Document Sent)
- (iv) PCT/IB/308 (Appln. sent to U.S.)
- (v) REQUEST FOR PUBLICATION OF ASSIGNMENT INFORMATION

Express Mail Mailing Label
No.: EL 874 117 723 US
Date of Deposit: December 7, 2001

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Asst. Commissioner for Patents, Washington, D.C. 20231.


Laraine Dobies

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

10/018238

INTERNATIONAL APPLICATION NO.
PCT/EP00/05341

ATTORNEY'S DOCKET NUMBER

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21. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO..... \$1040.00International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO \$890.00International preliminary examination fee (37 CFR 1.482) not paid to USPTO
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00International preliminary examination fee (37 CFR 1.482) paid to USPTO
but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00International preliminary examination fee (37 CFR 1.482) paid to USPTO
and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00**ENTER APPROPRIATE BASIC FEE AMOUNT =****CALCULATIONS PTO USE ONLY**

\$ 890.00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(e)).

\$ --

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	6 - 20 =	0	x \$18.00	\$ --
Independent claims	1 - 3 =	0	x \$84.00	\$ --
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$280.00	\$
TOTAL OF ABOVE CALCULATIONS =				\$ 890.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ --
SUBTOTAL =				\$ 890.00
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ --
TOTAL NATIONAL FEE =				\$ 890.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$ --
TOTAL FEES ENCLOSED =				\$ 890.00
				Amount to be refunded: \$
				charged: \$

\$

Total claims

6 - 20 =

0

x \$18.00

\$ --

Independent claims

1 - 3 =

0

x \$84.00

\$ --

MULTIPLE DEPENDENT CLAIM(S) (if applicable)

+ \$280.00

\$

TOTAL OF ABOVE CALCULATIONS =

\$ 890.00

☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.

\$ --

SUBTOTAL =

\$ 890.00

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(f)).

\$ --

TOTAL NATIONAL FEE =

\$ 890.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +

\$ --

TOTAL FEES ENCLOSED =

\$ 890.00

Amount to be
refunded:

\$

charged:

\$

a. ☒ A check in the amount of \$ 890.00 to cover the above fees is enclosed.b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1378. A duplicate copy of this sheet is enclosed.d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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New York, NY 10017-2023

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PATENT TRADEMARK OFFICE

Date: December 7, 2001

SIGNATURE

MARSHALL J. CHICK

NAME

26,853

REGISTRATION NUMBER

10/018238

JC13 Rec'd PCT/PTO 07 DEC 2001

Attorney Docket No. 01795/HG

**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

Applicant(s): Kevan HATCHMAN et al.

Serial No. : To be assigned (U.S.
National Phase of
PCT/EP00/05341
filed June 9, 2000)

Filed : CONCOMITANTLY HERewith

For : PERSONAL CARE FORMULATIONS

Art Unit :

Examiner :

ATTENTION BOX PCT

**PRELIMINARY AMENDMENT FILED CONCOMITANT
WITH NATIONAL PHASE PCT APPLICATION**

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

This is a PRELIMINARY AMENDMENT filed in the above-
referenced national phase PCT application being filed
concurrently herewith.

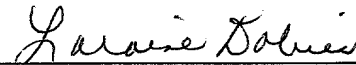
Please amend as follows:

IN THE SPECIFICATION:

Before the first paragraph of the specification insert the
following paragraph: --This application is a U.S. National Phase
Application under 35 USC 371 of International Application
PCT/EP00/05341 (published in English) filed June 9, 1999.--

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Date of Deposit: December 7, 2001

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deposited with the United States Postal
Service "Express Mail Post Office to
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Washington, D.C. 20231


Laraine Dobies

In the event that this Paper is late filed,
and the necessary petition for extension of
time is not filed concurrently herewith,
please consider this as a Petition for the
requisite extension of time, and to the
extent not tendered by check attached
hereto, authorization to charge the
extension fee, or any other fee
required in connection with this Paper
to Account No. 06-1378.

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IN THE CLAIMS:

Cancel claim 4.

Add the following new claims 6 and 7:

6. (New) A composition according to claim 1 wherein the oil comprises at least 16% based on the weight of oil, of a mineral oil.

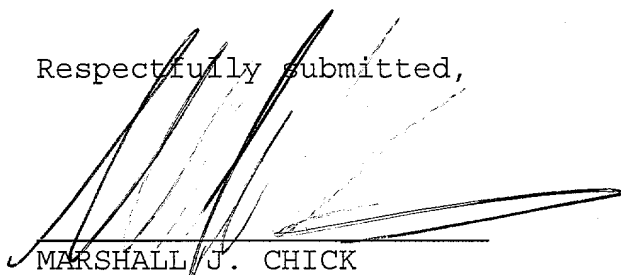
7. (New) A composition according to claim 3 wherein the oil comprises at least 16% based on the weight of oil, of a mineral oil.

R E M A R K S

Entry of this AMENDMENT and a favorable action on the merits
are respectfully requested.

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MJC/ld

Respectfully submitted,


MARSHALL J. CHICK
Reg. No. 26,853

PERSONAL CARE FORMULATIONS

The present invention relates to shampoo or cleaning compositions suitable for personal care applications in the form of I_1 mesophase systems containing dispersed oil.

Dispersing oil in aqueous shampoo and body wash formulations has presented problems. To prevent the oil phase separating it must either be: (A) emulsified which involves dispersing the oil as colloidal single droplets; (B) microemulsified which involves forming a micellar solution with oil incorporated into surfactant micelles; (C) suspended in a structured surfactant system which typically comprises a dispersion of a surfactant mesophase in aqueous electrolyte; or (D) incorporated into a water soluble solid, pasty or gelatinous composition.

With the exception of microemulsions which are clear, thermodynamically stable, micellar solutions, the foregoing systems are necessarily opaque and contain the oil dispersed in a relatively coarse form, which does not deposit satisfactorily on skin or hair.

However microemulsions are difficult to formulate using the surfactants which are most effective in body wash and other personal care formulations and contain relatively low concentrations of surfactant.

We have now discovered that oil may be stably incorporated into the structure of an I_1 phase to form a clear gel-like composition which contains higher concentrations of surfactant and oil than conventional microemulsions, but which dissolves in water to form a microemulsion. The novel oil-in- I_1 compositions also form microemulsions on heating.

Surfactants are known to form mesophases or liquid crystal phases at concentrations above approximately 30% by weight based on the weight of water and surfactant. Mesophases are phases which exhibit a degree of order intermediate between typical liquids and solids. Generally mesophases combine long range order associated with crystals, with fast molecular motion common to liquids.

The formation of detergent mesophases is well documented. Different surfactants and surfactant mixtures differ widely in their ability to form the numerous different mesophases, and in respect of the conditions of concentration and temperature at which they are formed. For a typical surfactant of the type normally used in cleaning products the following mesophases are usually observed. The concentrations given are illustrative only and may vary considerably from one surfactant or surfactant mixture to the next.

Below approximately 30% surfactant an isotropic L_1 phase is formed (with micelles of surfactant in water). Above 30% surfactant many detergents form a M phase which is not normally used in personal care applications since it does not show suitable flow characteristics and is difficult to dissolve or disperse in water. Above the concentrations required to form an M phase, but usually at concentrations of less than 80% active surfactant, i.e. 60%-80% a G-phase is formed. At concentrations higher than those required to form a G-phase, i.e. typically greater than 80% active surfactant, most surfactants form a hydrated solid, and some, especially non-ionic surfactants form a liquid phase containing dispersed micelle sized droplets of water - an inverted micellar solution known as an L_2 phase. L_2 detergent systems do not disperse readily in water and have a tendency to form undesirable gels, e.g. M phases, on dilution.

Some surfactants form viscous isotropic or VI phases. These are immobile phases usually with a vitreous appearance, and have been relatively little studied compared to the other phases discussed above. They have been virtually ignored in the context of formulating cleaning compositions because most of the surfactants and surfactant systems which are commonly used in cleaning compositions do not form VI phases, at least at

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normal temperatures, or form them only within narrow concentration ranges and because their known properties as immobile gels has deterred formulators from investigating them. They are recognised as being the most viscous of the lyotropic mesophases.

The different surfactant phases can be recognised by a combination of appearance, rheology, textures under the microscope, electron microscopy and x-ray diffraction or neutron scattering. A detailed description, with illustrations, of the difference textures observable using a polarising microscope, is to be found in the paper by Rosevear JAOCS Vol 31, p628.

The following terms may require explanation or definition:

The "hydrophilic: lipophilic balance", or "HLB" value is used as a measure of the relative affinities of the surfactants for water and oil respectively and correlates with their effectiveness as emulsifiers. HLB value can easily be calculated for alcohol ethoxylates since it is one fifth of the weight percent of ethylene oxide based on the total mole weight. Other surfactants can be assigned equivalent values by applying more complicated formulae or by measuring their relative affinity for water and oil. An HLB value of 20 represents a completely water soluble oil insoluble surfactant, while an HLB value of 0 represents a completely oil soluble and water insoluble surfactant.

"Optically isotropic" surfactant phases do not normally tend to rotate the plane of polarisation of plane polarised light. If a drop of sample is placed between two sheets of optically plane polarising material whose planes are at right angles, and light is shone on to one sheet, optically isotropic surfactant samples do not appear substantially brighter than their surrounding when viewed through the other sheet. Optically anisotropic materials appear substantially brighter. Optically anisotropic mesophases typically show characteristic textures when viewed through a microscope between crossed polarisers, whereas optically isotropic phases usually show a featureless continuum.

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"Newtonian liquids" have a viscosity which remains constant at different shear rates. For the purpose of this specification, liquids are considered Newtonian if the viscosity does not vary substantially at shear rates up to 1000 sec^{-1} .

"Lamellar" phases are phases which comprise a plurality of bilayers of surfactant arranged in parallel and separated by liquid medium. They include both solid phases and the typical form of the liquid crystal G-phase. G-phases are typically pourable, non-Newtonian, anisotropic products. They are typically viscous-looking, opalescent materials with a characteristic "smeary" appearance on flowing. They form characteristic texture under the polarising microscope and freeze fractured samples have a lamellar appearance under the electron microscope. X-ray diffraction or neutron scattering similarly reveal a lamellar structure, with a principal peak typically between 4 and 10nm, usually 5 to 6nm. Higher order peaks, when present occur at double or higher integral multiples of the Q value of the principal peak. Q is the momentum transfer vector and is related, in the case of lamellar phases, to the repeat spacing d by the equation $Q = \frac{2n}{d} [\pi]$ where n is the order of the peak.

G-phases, however, can exist in several different forms, including domains of parallel sheets which constitute the bulk of the typical G-phases described above and spherulites formed from a number of concentric spheroidal shells, each of which is a bilayer of surfactant. In this specification the term "lamellar" will be reserved for compositions which are at least partly of the former type. Opaque compositions at least predominantly of the latter type in which the continuous phase is a substantially isotropic solution containing dispersed spherulites are referred to herein as "G-phase compositions". G-phases are sometimes referred to in the literature as $L_{(\alpha)}$ phases.

L_1 -phases are mobile, optically isotropic, and typically Newtonian liquids which show no texture under the polarising microscope. Electron microscopy is capable of resolving the texture of such phases only at very high magnifications, and X-ray or neutron scattering normally gives only a single broad peak typical of a liquid structure, at very small angles

close to the reference beam. The viscosity of an L_1 -phase is usually low, but may rise significantly as the concentration approaches the upper phase boundary.

"M-phases" are typically immobile, anisotropic products resembling low melting point waxes. They give characteristic textures under the polarising microscope, and a hexagonal diffraction pattern by X-ray or neutron diffraction which comprises a major peak, usually at values corresponding to a repeat spacing between 4 and 10nm, and sometimes higher order peaks, the first at a Q-value which is $3^{0.5}$ times the Q-value of the principal peak and the next double the Q-value of the principal peak. M-phases are sometimes referred to in the literature as H-phases.

The viscous isotropic or "VI" phases are typically immobile, non-Newtonian, optically isotropic and are typically transparent, at least when pure. VI phases have a cubic symmetrical diffraction pattern, under X-ray diffraction or neutron scattering, with a principal peak and higher order peaks at $2^{0.5}$ and $3^{0.5}$ times the Q-value of the principal peak.

These cubic liquid crystalline phases are sometimes observed immediately following the micellar phase at ambient temperature as the concentration of surfactant is increased. It has been proposed that such VI phases, sometimes referred to as I_1 phase, may arise from the packing of micelles (probably spherical) in a cubic lattice. At ambient temperature a further increase in surfactant concentration usually results in hexagonal phase (M_1), which may be followed by a lamellar phase (G). I_1 phases, when they occur, are usually only observed over a narrow range of concentrations, typically just above those at which the L_1 -phase is formed. The location of such VI phases in a phase diagram suggests that the phase is built up of small closed surfactant aggregates in a water continuum.

An inverse form of the I_1 phase (the I_2 phase) has also been reported, possibly between the inverse hexagonal (M_2) and L_2 phases. It consists of a surfactant continuum containing a cubic array of inverted micelles. An alternative form of the VI phase called

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the V_1 phase has been observed at concentrations between the M and G phases and may comprise a bicontinuous system. This may exhibit an even higher viscosity than the I_1 . An inverse phase, the V_2 phase, between the G and M_2 phases has also been postulated.

VI phases are typically examples of "ringing gels". When a jar or beaker containing such a phase is sharply struck, a distinctive vibration can be felt in the composition.

The I_1/L_1 transition temperature will be referred to herein as the melting point of the I_1 phase for convenience, although it is not strictly speaking the melting point since the VI phases are not solids.

All references herein to the formation or existence of specific phases or structures are to be construed, unless the context requires otherwise, as references to their formation or existence at 20°C.

Hexagonal gels (M-phase) have been referred to in the prior art as cleaning compositions, e.g. GB 2 179 055, EP I 153 837 and colloidal gels formed with gelling agents such as synthetic polymers or gelatin have also been suggested, e.g. US 4 465 663.

However these compositions cannot be readily dissolved in water to form microemulsions. They are moreover usually opaque and of an unattractive appearance and often require the presence of solvents such as glycols which add to the cost and are environmentally undesirable.

The use of a type of ringing gel to suspend oil for cosmetic or pharmaceutical applications was described in US 4 026 818 but the formulation requires the presence of hydroxylic solvents and utilises a surfactant system which is unsuitable for shampoo applications. EP O 598 335 describes the use of various cubic phases including I_1 phases as laundry prespotters and for other cleaning formulations. It does not suggest how such phases could be used to suspend oil or form microemulsions. Normally attempts to

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suspend oil in surfactant mesophases result in coarse droplets of oil being suspended in the aqueous phase of a structured surfactant.

Our invention provides a concentrated personal cleansing composition comprising, by weight of the composition, at least 20% water, 10 to 40% total surfactant and 2 to 40% of oil, such as a mineral, fatty ester, glyceride, terpene or silicone oil wherein said surfactant comprises (A) an oil soluble surfactant having an HLB of from 2 to 10 in a proportion of from 8:1 to 1:5 based on the weight of oil and (B) a hydrophilic surfactant having an HLB greater than 11, in a weight proportion of from 1:1 to 1:30 based on the weight of (A), said surfactant water and oil being present in proportions adapted to form an I_1 phase having an I_1/L_1 transition temperature greater than 25°C.

The surfactants are preferably selected to provide an I_1 phase over a comparatively broad surfactant concentration range e.g. more than $\pm 5\%$ or greater, which range typically lies above 15% by weight total surfactant based on the weight of the composition e.g. between 20% and 40% by weight surfactant usually between 25% and 60%.

The surfactants are preferably selected to provide an I_1 phase which melts above 30°C e.g. above 35°C, most preferably above 40°C. Preferably the I_1 phase melts at a temperature substantially below 100°C, e.g. below 90°C, more preferably below 80°C, most preferably below 70°C, especially below 60°C, typically below 55°C, usually below 50°C.

The surfactant mixture preferably has a mean HLB based on the molar proportions of the components between 10 and 15 e.g. 11 to 14. The surfactants preferably comprise non-ionic surfactants such as ethoxylated alcohols. It has been found that highly ethoxylated fatty alcohols, e.g. more than 10 EO groups, preferably more than 15 EO groups, especially 18 to 50 EO groups form I_1 phases particularly readily.

Other non-ionic surfactants which may be present include:-

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alkyl phenol ethoxylates, fatty acid ethoxylates, fatty acid monoalkylolamide ethoxylates, fatty alcohol propoxylates, fatty anime alkoxyates and fatty acid glyceryl ester ethoxylates. Other non-ionic compounds suitable for inclusion in compositions of the present invention include mixed ethylene oxide propylene oxide block copolymers, low relative molecular mass polyethylene glycols e.g. PEG600 and PEG200, ethylene glycol monoesters, amine oxides and alkyl polyglycosides, alkyl sugar esters including alkyl sucrose esters and alkyl oligosaccharide ester, alkyl capped polyvinyl alcohol and alkyl capped polyvinyl pyrrolidone.

Compositions of the invention may also comprise anionic surfactants, in addition to or instead of non-ionic surfactants. Anionic surfactant may comprise a C₁₀₋₂₀ alkyl benzene sulphonate or an alkyl ether sulphate which is preferably the product obtained by ethoxylating a natural fatty or synthetic C₁₀₋₂₀ e.g. a C₁₂₋₁₄ alcohol with from 1 to 20, preferably 2 to 10 e.g. 3 to 4 ethyleneoxy groups, optionally stripping any unreacted alcohol, reacting the ethoxylated product with a sulphating agent and neutralising the resulting alkyl ether sulphuric acid with a base. The term also includes alkyl glyceryl sulphates, and random or block copolymerised alkyl ethoxy/propoxy sulphates.

The anionic surfactant may also comprise, for example, C₁₀₋₂₀ e.g. C₁₂₋₁₈ alkyl sulphate.

The surfactant may comprise a C₈₋₂₀ e.g. C₁₀₋₂₀ aliphatic soap. The soap may be saturated or unsaturated, straight or branched chain.

Preferred examples include dodecanoates, myristates, stearates, oleates, linoleates, linoleates and palmitates and coconut and tallow soaps.

The surfactant may include other anionic surfactants, such as olefin sulphonates, paraffin sulphonates, taurides, isethionates, ether sulphonates, ether carboxylates, aliphatic ester sulphonates e.g. alkyl glyceryl sulphonates, sulphosuccinates or sulphosuccinamates.

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The cation of any anionic surfactant is typically sodium but may alternatively be potassium, lithium, calcium, magnesium, ammonium, or an alkyl ammonium having up to 6 aliphatic carbon atoms including isopropyl ammonium, monoethanol ammonium, diethanol ammonium, and triethanol ammonium.

Ammonium and ethanol ammonium salts are generally more soluble than the sodium salts. Mixtures of the above cations may be used.

The composition may contain amphoteric surfactants such as betaines sulphobetaines, amido betaines or imidazoline betaines.

The I₁ phase may be conveniently prepared by mixing the oil and oil soluble surfactant and adding sufficient water to the water soluble surfactant to maintain a lamellar phase. The oil and oil soluble surfactant may be stirred into the lamellar composition at elevated temperature, above the melting point of the desired I₁ phase. The composition is then diluted with hot water until a microemulsion is formed and then cooled to solidify it into the I₁ phase.

The oil is preferably a mineral oil (e.g. a low molecular weight petroleum ether having, for example, a boiling point below 120°C e.g. below 100°C especially below 80°C) or a lower molecular weight fatty ester (e.g. one having less than 25 carbon atoms) such as isopropyl esters of lauric isostearic or palmitic acids or their ethyl analogues. Other oils, including higher mol weight fatty esters, e.g. oleyl oleate, fatty glycerides, terpene oils such as limonene or silicone oils may present difficulties in providing clear compositions. Such oils can nevertheless be incorporated in clear formulations by blending with sufficient mineral oil (preferably low molecular weight mineral oil). The amount required varies according to the nature of the oil. Typically the blend contains at least 16%, based on the total weight of oil, of the mineral oil, especially 30 to 80%, typically 40 to 60%. Particularly preferred are vegetable oils such as coconut, evening primrose, groundnut, meadow foam, apricot kernel, peach kernel, avocado, jojoba and olive oil.

Oil soluble cosmetic or topical pharmaceutical ingredients may be dissolved in the oil including antiseptics, styptics, antidandruff agents such as zinc omadine (zinc pyrithione) and selenium disulphide, proteins, emollients such as lanolin, isopropyl myristate, glyceryl isostearate or propylene glycol distearate, dyes, perfumes and waxes. Water insoluble particulate solids including exfoliants such as talc, clays, polymer beads, sawdust, silica, seeds, ground nutshells and dicalcium phosphate, pearlisers such as mica or glycerol or ethylene glycol mono- or di-stearate, glitter additives and sunscreens such as titanium dioxide may be dispersed in the hot microemulsion prior to cooling. Porous particles (so called micro-sponges) containing absorbed active ingredients or gelatin or other microcapsules may be suspended. Other active ingredients which may be suspended include insect repellants and topical pharmaceutical preparations, e.g. preparations for treatment of acne, fungicides for athlete's foot or ringworm or antiseptics or antihistamines. Pigments, such as the iron oxides, may also be added.

Electrolytes tend to break I₁ phase structure and are preferably present in concentrations below 10% based on total weight of the compositions, more preferably below 5%, e.g. 0 to 3%, most preferably 0 to 1%. Generally we prefer that electrolyte be substantially absent. Adventitious chloride or sulphate present as impurities in the surfactant can be tolerated. Small amounts of builder such as citrates, pyrophosphates, polyphosphates may optionally be included.

Water soluble solvents are generally undesirable and are not required to form stable I₁ structures according to the invention. We therefore prefer that they should be substantially absent. Although small amounts of, for example, ethanol or propanol or of a water miscible polyhydric alcohol or alcohol ester may sometimes be desired for special purposes, they are preferably present in amounts less than 5% by weight, more preferably less than 3% by weight, most preferably less than 2% by weight, e.g. less than 1% by weight.

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The composition may optionally contain hydrotropes such as sodium lower alkyl benzene sulphonate e.g. sodium toluene, xylene or cumene sulphonate or urea, however these are not generally necessary and are not generally preferred. We prefer that these should be present in quantities less than 5% by weight, more preferably less than 4%, especially less than 2% e.g. 0 to 1%. They may be useful occasionally to avoid haziness of the gel.

The total amount of water is preferably from 25 to 60% by weight of the composition, more preferably 30 to 50%, e.g. 35 to 50%. The total weight percentage of surfactant based on the weight of the composition is preferably from 15 to 35%, e.g. 20 to 30%. The proportion of oil is preferably greater than 5%, more preferably greater than 8%, e.g. 10 to 30%, especially 15 to 25% by weight based on the weight of the composition. The oil soluble surfactant is preferably present in a proportion of more than 1:5 based on the weight of oil, more preferably from 1:2 to 5:1. The oil soluble surfactant preferably has an HLB of from 3 to 9 e.g. 4 to 8.

The weight ratio of water soluble surfactant to oil soluble surfactant is preferably 1:1 to 30:1, more preferably 2:1 to 20:1, typically 3:1 to 15:1, e.g. 4:1 to 10:1. The water soluble surfactant preferably has an HLB greater than 12, more preferably greater than 13, especially 14 to 19.

The product may be cast into shaped bodies or formed into particles or granules, e.g. by spray cooling a hot solution of the L_1 phase formed on melting the composition.

The composition may be converted into a microemulsion phase by addition of water, by heating above the melting point or by adding electrolyte such as salt and the invention includes L_1 phases when so prepared.

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The invention will be illustrated by the following examples:

Example 1

The following ingredients were mixed at 60°C and cooled to form a ringing gel:

<u>Component</u>	<u>Solids (%)</u>	<u>w/w (%)</u>
MINERAL OIL (100%)	20	20
"EMPICOL"® 0251/70J (70%)	11.2	16
"EMPIGEN"® BB (30%)	4.8	16
"GLUCAPON"® 215 CS UP (65%)	6	9.2
"EMPILAN"® KB2 (100%)	7.5	7.5
SODIUM CHLORIDE (100%)	2	2
PERFUME (100%)	0.5	0.5
ETHYLENE DIAMINE TETRACETIC ACID (100%)	0.1	0.1
CITRIC ACID (100%)	0.2	0.2
BENZOIC ACID (100%)	0.3	0.3
SODIUM HYDROXIDE (47%)	0.1	0.2
WATER	---	Balance

The method of mixing comprised the following steps:-

1. Charge 50% of water
2. Heat to 60°C
3. Add EDTA, sodium benzoate, citric acid and 47% NaOH dissolve with stirring
4. Add "EMPIGEN" BB
5. Add mineral oil and disperse with stirring
6. Add "EMPILAN" KB 2 and mix thoroughly
7. Add "EMPICOL" 0251/70j
8. Add remaining water
9. Add "GLUCAPON" 215 CS UP
10. Add further KB 2 until clear
11. Cool
12. Add evaporated water
13. Adjust pH

Physical Data

pH (10%)	: 5.5 ± 0.1	Density @ 20°C	: 1.0 ± 0.1 g cm ⁻³
Solids (%)	: ~ 53% (typical)	Appearance	: Clear or Hazy Gel
Odour	: Characteristic	Set Point (typical)	: 30°C
Viscosity @ 20°C : N/A			

The product was examined by x-ray diffraction and exhibited peaks at 13.145nm (intense and sharp), 7.943nm (ill defined) and 6.355nm (small), indicating cubic symmetry, and formed a clear microemulsion on dilution or heating. The latter gave good even distribution of oil applied to skin.

Example 2

The following ingredients were mixed at 60°C and cooled to form a ringing gel:

<u>Component</u>	<u>Solids (%)</u>	<u>w/w (%)</u>
MINERAL OIL (100%)	15	15
"EMPICOL"® CDL30J/35 (22%)	8	35.4
"EMPIGEN"® BB (30%)	8	26.7
"EMPICOL"® 0785 (40%)	2	5
"EMPILAN"® KB2 (100%)	6	6
"EMPILAN"® KB6 (100%)	6	6
CITRIC ACID (100%)	0.5	0.5
PERFUME (100%)	0.2	0.2
ETHYLENE DIAMINE TETRACETIC ACID (100%)	0.2	0.2
"KATHON"®	---	0.2
WATER	---	Balance
TOTAL	45.8	100

Physical Data

Appearance	: Clear Liquid/Gel	Odour	: Characteristic Odour
Solids	: 36.5% (typical)	pH (100%)	: 5.5 - 6.5 (typical)
Odour	: Characteristic	Set Point	: 20 ± 5°C

Viscosity (Carrimed Rheometer @ 20°C : N/A)

The product had small angle x-ray diffraction peaks characteristic of cubic symmetry and formed a clear microemulsion on dilution with water or warming. The latter gave good even deposition of oil on skin.

Examples 3 and 4

The following ingredients were mixed at 60°C and cooled to form ringing gels:

Component	1		2	
	Solids (%)	w/w (%)	Solids (%)	w/w (%)
"EMPIGEN"® CDL30J/35 (22%)	8	36.4	8	36.4
"EMPIGEN"® BB (30%)	8	26.7	8	26.7
"EMPICOL"® LB40 (40%)	4	7.5	3	7.5
"EMPICOL"® CVH (90%)	4	4	---	---
"EMPILAN"® KB2 (100%)	5.5	5.5	6	6
TRIETHANOLAMINE (100%)	1.1	1.1	---	---
CITRIC ACID	1	0.75	0.75	0.75
ETHYLENE DIAMINE				
TETRACETIC ACID	0.05	0.05	0.05	0.05
"KATHON"® CG (100%)	0.05	0.05	0.05	0.05
LIGHT MINERAL (100%)	14	14	20	20
WATER	---	Balance	---	Balance
TOTAL	45.7	100	46.1	100
Appearance	Clear Gel		Clear Gel	

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Example 5

<u>Component</u>	<u>Solids (%)</u>	<u>W/W (%)</u>
LIGHT MINERAL OIL ("KRISTOL"® M14) (100 %)	18	18
"EMPICOL"® 0251 70 J (70 %)	12	17.2
"EMPICOL"® CED5 FL (100 %)	5	5
"EMPILAN"® KBE2 (100 %)	3	3
"EMPILAN"® KB6 (100 %)	3	3
"EMPIGEN"® BB (30 %)	3	10
SODIUM CHLORIDE (100 %)	4	4
GLYCEROL (100 %)	2	2
SODIUM HYDROXIDE (50 %)	0.4	0.8
ETHYLENE DIAMINE TETRACETIC ACID (100 %) Na SALT	0.1	0.1
CITRIC ACID (100 %)	0.2	0.2
SODIUM BENZOATE (100 %)	0.3	0.3
WATER	-	Balance

Example 6

<u>Component</u>	<u>Solids (%)</u>	<u>W/W (%)</u>
HEAVY MINERAL OIL (“KRISTOL” ® M70) (100 %)	18	18
“EMPICOL” ® 0251 70 J (70 %)	10.5	15
“EMPICOL” ® CED5 FL (100 %)	6	6
“EMPILAN” ® KB2 (100 %)	3.5	3.5
“EMPILAN” ® KB12 (100 %)	5	5
“EMPIGEN” ® BB (30 %)	3	10
SODIUM CHLORIDE (100 %)	4	4
GLYCEROL (100 %)	2	2
SODIUM HYDROXIDE (50 %)	0.5	1.0
ETHYLENE DIAMINE TETRACETIC ACID (100 %) Na SALT	0.1	0.1
CITRIC ACID (100 %)	0.2	0.2
SODIUM BENZOATE (100 %)	0.3	0.3
WATER	-	Balance

Physical Data

Density @ 20°C : 1.0 +/- 0.1

pH (10 %) : 5.5 +/- 0.5

Appearance: Clear or hazy gel

Odour : Characteristic

Set point (typical): 35 +/- 5°C

Viscosity @ 20°C: N/A

Method for examples 5 and 6

- i) Charge water and heat to 60°C.
- ii) Add EDTA, sodium benzoate, citric acid and NaOH. Dissolve with stirring.
- iii) Add "EMPICOL" CED5 FL and mix thoroughly.
- iv) Add glycerol.
- v) Add NaCl and disperse with stirring.
- vi) Add "EMPILAN" KBE2 and "EMPILAN" KB6 or "EMPILAN" KB12. Disperse with stirring.
- vii) Add "EMPIGEN" BB.
- viii) Add mineral and disperse with stirring.
- ix) Add "EMPICOL" 0251 70J and disperse with stirring.
- x) Add additional nonionic surfactant to clear (if necessary).
- xi) Cool to 40°C.
- xii) Add evaporated water
- xiii) Adjust pH and offload.

Example 7

<u>Component</u>	<u>Solids (%)</u>	<u>W/W (%)</u>
LIGHT MINERAL OIL ("KRISTOL" ® M14) (100 %)	9	9
DOW CORNING DC 556 SILICONE FLUID (100 %)	9	9
"EMPICOL" 0251 70 J (70 %)	12	17.2
"EMPICOL" CED5 FL (100 %)	5	5
"EMPILAN" KB2 (100 %)	3.5	3.5
"EMPILAN" KB12 (100 %)	3.5	3.5
"EMPIGEN" BB (30 %)	3	10
SODIUM CHLORIDE (100 %)	4	4
GLYCEROL (100 %)	2	2
SODIUM HYDROXIDE (50 %)	0.4	0.8
ETHYLENE DIAMINE TETRACETIC ACID (100 %) Na SALT	0.1	0.1
CITRIC ACID (100 %)	0.2	0.2
SODIUM BENZOATE (100 %)	0.3	0.3
WATER	-	Balance

The formulation forms a microemulsion at 60°C and forms a gel when cooled to ambient temperature.

Example 8

<u>Component</u>	<u>Solids (%)</u>	<u>W/W (%)</u>
HEAVY MINERAL OIL ("KRISTOL"® M70) (100 %)	15	15
"CERAPHYL"® GA-D (100 %)	5	5
"EMPICOL" 0251 70 J (70 %)	12	17.2
"EMPICOL" CED5 FL (100 %)	5	5
"EMPILAN" KBE2 (100 %)	3.0	3.0
"EMPILAN" KB12 (100 %)	4.5	4.5
"EMPIGEN" BB (30 %)	3	10
SODIUM CHLORIDE (100 %)	4	4
GLYCEROL (100 %)	2	2
SODIUM HYDROXIDE (50 %)	0.4	0.8
ETHYLENE DIAMINE TETRACETIC ACID (100 %) Na SALT	0.1	0.1
CITRIC ACID (100 %)	0.2	0.2
SODIUM BENZOATE (100 %)	0.3	0.3
WATER	-	Balance

A hazy/opaque emulsion is formed at 60°C and cools to form a clear 'ringing' gel at ambient temperature.

Physical Data

Density @ 20°C : 1.0 +/- 0.1

pH (10 %) : 5.5 +/- 0.5

Appearance: Clear or hazy gel

Odour : Characteristic

Set point (typical): 35 +/- 5°C

Viscosity @ 20°C: N/A

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Method for examples 7 and 8

- i) Charge water and heat to 60°C.
- ii) Add EDTA, sodium benzoate, citric acid and NaOH. Dissolve with stirring.
- iii) Add "EMPICOL" CED5 FL and mix thoroughly.
- iv) Add glycerol.
- v) Add NaCl and disperse with stirring.
- vi) Add "EMPILAN" KBE2 and "EMPILAN" KB12. Disperse with stirring.
- vii) Add "EMPIGEN" BB.
- viii) Blend 50/50 oil phase - oil and cosmetic ingredient. Add to aqueous surfactant solution. Disperse with stirring to form homogeneous emulsion.
- ix) Add "EMPICOL" 0251 70J and disperse.
- x) Cool to 40°C.
- xi) Add evaporated water.
- xii) Adjust pH and offload.

If gel is opaque, re-heat and add additional nonionic surfactant or water.

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Example 9

Component	Solids (%)	W/W (%)
LIGHT MINERAL OIL ("KRISTOL" ® M14) (100 %)	10	10
"MIGLYOL" ® 810/812S	10	10
"EMPICOL" ® 0251 70 J (70 %)	11	15.7
"EMPICOL" ® CED5 FL (100 %)	6	6
"EMPILAN" ® KBE2 (100 %)	3.5	3.5
"EMPILAN" ® KB12 (100 %)	3.5	3.5
"EMPIGEN" ® BB (30 %)	3	10
SODIUM CHLORIDE (100 %)	5	5
GLYCEROL (100 %)	1	1
SODIUM HYDROXIDE (50 %)	0.5	1
ETHYLENE DIAMINE TETRACETIC ACID (100 %) Na SALT	0.1	0.1
CITRIC ACID (100 %)	0.2	0.2
SODIUM BENZOATE (100 %)	0.3	0.3
WATER	-	Balance

Hazy emulsion clears to form a microemulsion on cooling and 'ringing' gel is obtained at ambient temperature.

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Example 10

Component	Solids (%)	W/W (%)
LIGHT MINERAL OIL ("KRISTOL" ® M14) (100 %)	10	10
"MIGLYOL" ® 818 (100 %)	10	10
"EMPICOL" ® 0251 70 J (70 %)	11	15.7
"EMPICOL" ® CED5 FL (100 %)	6	6
"EMPILAN" ® KBE2 (100 %)	3.5	3.5
"EMPILAN" ® KB12 (100 %)	5	5
"EMPIGEN" ® BB (30 %)	3	10
SODIUM CHLORIDE (100 %)	5	5
GLYCEROL (100 %)	1	1
SODIUM HYDROXIDE (50 %)	0.5	1
ETHYLENE DIAMINE TETRACETIC ACID (100 %) Na SALT	0.1	0.1
CITRIC ACID (100 %)	0.2	0.2
SODIUM BENZOATE (100 %)	0.3	0.3
WATER	-	Balance

Forms a microemulsion at 60°C and a 'ringing' gel is obtained after cooling.

Example 11

Component	Solids (%)	W/W (%)
LIGHT MINERAL OIL ("KRISTOL" ® M14) (100 %)	10	10
"MIGLYOL" ® 840	10	10
"EMPICOL" ® 0251 70 J (70 %)	11	15.7
"EMPICOL" ® CED5 FL (100 %)	6	6
"EMPILAN" KBE2 (100 %)	3.5	3.5
"EMPILAN" ® KB12 (100 %)	5	5
"EMPIGEN" ® BB (30 %)	3	10
SODIUM CHLORIDE (100 %)	5	5
GLYCEROL (100 %)	1	1
SODIUM HYDROXIDE (50 %)	0.5	1
ETHYLENE DIAMINE TETRACETIC ACID (100 %) Na SALT	0.1	0.1
CITRIC ACID (100 %)	0.2	0.2
SODIUM BENZOATE (100 %)	0.3	0.3
WATER	-	Balance

Physical Data

Density @ 20°C : 1.0 +/- 0.1

pH (10 %) : 5.5 +/- 0.5

Appearance: Clear or hazy gel

Odour : Characteristic

Set point (typical): 35 +/- 5°C

Viscosity @ 20°C: N/A

Method for examples 9, 10 and 11

- i) Blend 50/50 oil phase – oil and cosmetic ingredient. Heat to 60°C.
- ii) Add glycerol and stir to disperse.
- iii) Add “EMPILAN” KBE2 and “EMPILAN” KB12. Disperse with stirring.
- iv) Add “EMPICOL” CED5 FL.
- v) Add “EMPIGEN” BB.
- vi) Add “EMPICOL” 0251 70J.
- vii) Add EDTA, citric acid, sodium benzoate and NaCl. Disperse with stirring.
- viii) Add water.
- ix) Add NaOH.
- x) Cool to 40°C.
- xi) Add evaporated water.
- xii) Adjust pH and offload.

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Example 12

Component	Solids (%)	W/W (%)
EMOLLIENT – FATTY ACID ESTER (100 %)	20	20
“EMPICOL” ® 0251 70 J (70 %)	12	17.2
“EMPICOL” ® CED5 FL (100 %)	5	5
“EMPILAN” ® KB6 (100 %)	5	5
“EMPIGEN” ® BB (30 %)	3	10
SODIUM CHLORIDE (100 %)	5	5
GLYCEROL (100 %)	1	1
SODIUM HYDROXIDE (50 %)	0,4	0.8
ETHYLENE DIAMINE TETRACETIC ACID (100 %) Na SALT	0.1	0.1
CITRIC ACID (100 %)	0.2	0.2
SODIUM BENZOATE (100 %)	0.3	0.3
WATER	-	Balance

Clear gels have been prepared using the following fatty acid esters:

Isopropyl laurate (“ESTOL” ® IPL 1505)
 Isopropyl myristate (“ESTOL” ® IPM 1512)
 Isopropyl palmitate (“ESTOL” ® IPP 1517)
 Isopropyl isostearate (“SCHERCOMOL” ® 318)

Physical Data

Density @ 20°C : 1.0 +/- 0.1

pH (10 %) : 5.5 +/- 0.5

Appearance: Clear or hazy gel

Odour : Characteristic

Set point (typical): 35 +/- 5°C

Viscosity @ 20°C: N/A

Method for example 12

- i) Heat oil phase to 60°C.
- ii) Add “EMPILAN” KB6 and stir to disperse.
- iii) Add glycerol and stir to disperse.
- iv) Add “EMPIGEN” BB.
- v) Add “EMPICOL” CED5 FL.

- vi) Add "EMPICOL" 0251 70J.
- vii) Add EDTA, NaCl, sodium benzoate and citric acid. Stir to disperse.
- viii) Add water.
- ix) Add NaOH.
- x) Cool to 40°C.
- xi) Add evaporated water.
- xii) Check pH (10 %).
- xiii) Adjust pH and offload.

The products in each case exhibited cubic symmetry and formed clear microemulsions or dilution with water or heating. The registered trade marks noted above have the following significance:-

"EMPICOL" CVH is a C₈ alkyl ether carboxylic acid

"EMPICOL" LB40 is a C₈ C₁₀ alkyl sulphate

"EMPICOL" 0251/70J is a C₁₂₋₁₄ alkyl 3 mole ethoxy sulphate

"EMPICOL" 9758 is a C₁₀ alkyl sulphate

"EMPICOL" CED 5FL is lauryl 6 mole ethoxy carboxylic acid

"EMPIGEN" BB is a C₁₂₋₁₄ alkyl betaine

"EMPIGEN" CDL is coconut amphi acetate

"EMPILAN" KB2 is a C₁₂₋₁₄ alkyl 2 mole ethoxylate

"EMPILAN" KB6 is a C₁₂₋₁₄ alkyl 6 mole ethoxylate

"EMPILAN" KB12 is a C₁₂₋₁₄ alkyl 12 mole ethoxylate

"GLUCAPON" 215CS is a C₈₋₁₀ alkyl polyclucoside D.P. 1.5

"KATHON" CG is a proprietary biocide

"DOW CORNING" DC556 is phenyl trimethicone

"CERAPHYL" GA-D is maleated soya bean oil

"MIGLYOL" 810/812S is capric/caprylic triglyceride

"MIGLYOL" is capric/caprylic/linoleic triglyceride

"MIGLYOL" 840 is dipropylene glycol dicaprylate/dicaprate

CLAIMS

1. A concentrated personal cleansing composition comprising, by weight of the composition, at least 20% water, 10 to 40% total surfactant and 2 to 40% of oil wherein said surfactant comprises (A) an oil soluble surfactant having an HLB of from 2 to 10 in a proportion of from 8:1 to 1:5 based on the weight of oil and (B) a hydrophilic surfactant having an HLB greater than 11, in a weight proportion of from 1:1 to 1:30 based on the weight of (A), said surfactant water and oil being present in proportions adapted to form an I_1 phase having an I_1/L_1 transition temperature greater than 25°C.
2. A composition according to claim 1 wherein the total surfactant has a mean HLB between 10 and 15.
3. A composition according to claim 1 wherein said oil comprises a mineral, fatty ester, glyceride, terpene or silicone oil
4. A composition according to either of claims 1 and 3 wherein the oil comprises at least 16% based on the weight of oil, of a mineral oil.
5. A method for preparing a composition according to claim 1 comprising : (i) forming a mixture (a) of said oil and said oil soluble surfactant; (ii) mixing said mixture (a) with a mixture (b) of said water soluble surfactant and sufficient water to form a lamellar phase with said water soluble surfactant; (iii) maintaining said mixture of (a) and (b) above the I_1/L_1 transition temperature of said composition while diluting said mixture of (a) and (b) with water to form said composition; and (iv) cooling said composition below the I_1/L_1 transition temperature.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Kevan Hatchman, Elvin Lukenbach, Laura McCulloch and Benjamin Wiegand

For: PERSONAL CARE FORMULATIONS

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is for the following type of application:

(check one applicable item below)☐

Original

☐

Divisional

☐

Continuation

☒

U.S. National Stage of PCT

☐

Continuation-in-Part

My residence, post office address and citizenship are as stated below next to my name; and I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a

☒

Utility Patent

☐

Design Patent

is sought on the invention, whose title appears above, the specification of which:

☐

is attached hereto

☒was filed on June 9, 2000, as U.S. Serial Number 10/018,238☐and was amended on _____ *(if applicable)*☐

was described and claimed in PCT International Application Number _____, filed on _____ and as amended under PCT Article 19 on _____ and/or PCT Article 34 on _____.

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I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to the patentability of this application in accordance with 37 CFR § 1.56.

**DISCLOSURE AND/OR CLAIM FOR PRIORITY UNDER
35 U.S.C. §§ 119(a)-(d) OF FOREIGN APPLICATIONS
FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN)
OF THIS APPLICATION**

I hereby claim foreign priority benefits under Title 35, United States Code §§ 119(a)-(d) of any foreign applications for patent, inventor's certificate or PCT international application designating at least one country other than the United States of America listed below and have also identified below any foreign application for patent, inventor's certificate or any PCT international application designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

Country (or indicate if PCT)	Application Number	Date of Filing (day, month, year)	Priority Claimed Under 37 USC 119a-d
Great Britain	9913408.2 ✓	June 10, 1999 —	<u>X</u> Yes — No
PCT	PCT/EP00/05341 ✓	June 9, 2000 ✓	<u>X</u> Yes — No
			— Yes — No
			— Yes — No

**DISCLOSURE OF FOREIGN APPLICATION(S) IF ANY,
FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN)
PRIOR TO THE OF THIS APPLICATION**

Country (or indicate if PCT)	Application Number	Date of Filing (day, month, year)

**CLAIM FOR PRIORITY OF UNITED STATES APPLICATIONS
OR PCT APPLICATIONS FILED
IN THE UNITED STATES RECEIVING OFFICE
UNDER 35 U.S.C. §120**

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Date Filed	Status Patented/Pending/Abandoned

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
UNDER 35 U.S.C. § 119(e)**

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application Number	Filing Date

POWER OF ATTORNEY

- ☐ I hereby appoint all the practitioners associated with Customer Number 23377 (which is the Customer Number assigned to Woodcock Washburn LLP) to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected therewith. Each practitioner associated with Customer Number 23377 is an attorney registered before the United States Patent and Trademark Office.

2337723377

PATENT TRADEMARK OFFICE

- ☒ I hereby appoint the following persons of the firm of **WOODCOCK WASHBURN LLP**, One Liberty Place - 46th Floor, Philadelphia, Pennsylvania 19103 as attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Attorney/Patent Agent	Registration No.
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Wendy A. Choi	<u>36,697</u>

- ☒ I hereby appoint the following persons of the firm of **JOHNSON & JOHNSON**, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003 as attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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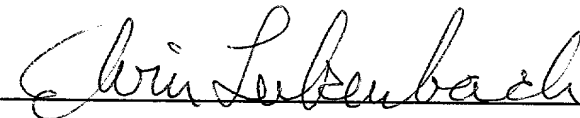
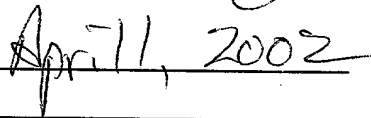
New Brunswick, NJ 08933-7003

10018238-041102

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first joint inventor**Kevan***(Given Name)**(Middle Initial or Name)***Hatchman***Family (or last name)***City/Country of Actual Residence: Worcestershire, Great Britain****Mailing Address:****5 Byland Close****Friarscroft, Bromsgrove****Worcestershire B61 7PL Great Britain *GBN*.****Country of Citizenship: Great Britain** ✓**Inventor's signature:** K. Hatchman**Date:** 2/4/02.10016338-04102
2007-04-02

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Full name of second joint inventor**Elvin***(Given Name)**(Middle Initial or Name)***Lukenbach***Family (or last name)***City/State of Actual Residence: Flemington, New Jersey****Mailing Address:****160 Klinesville Road****Flemington, New Jersey 08822 NJ.****Country of Citizenship: United States of America -****Inventor's signature:****Date:**

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Full name of third joint inventor**Laura***(Given Name)**(Middle Initial or Name)***McCulloch***Family (or last name)***City/State of Actual Residence: Cedar Knolls, New Jersey****Mailing Address:****Brookvale, Muss Lane****Kings Somborne****Hampshire****England S020 6PE UK 6BX****Country of Citizenship: United States of America ✓****Inventor's signature:****Date:**3/22/02

20018233-0440

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Full name of fourth joint inventor

4-00 Benjamin

(Given Name)

(Middle Initial or Name)

Wiegand

Family (or last name)

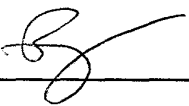
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Country of Citizenship: United States of America ✓

Inventor's signature: 

Date: 3/22/02

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